

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 27, 2015

## **MEMORANDUM**

Subject:

Acute Toxicity Review for EPA Reg. No. 9480-4

DP Barcode: D423596

From:

Chris Jiang, Chemist

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

Through:

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To:

Seiichi Murasaki PM 33/Terria Northern

Regulatory Management Branch I Antimicrobials Division (7510P)

Applicant:

Professional Disposables International, Inc.

#### FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> )	
dimethyl ethylbenzyl ammonium chlorides	0.25
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> , 5% C <sub>12</sub> , 5 % C <sub>18</sub> )	
dimethyl ethylbenzyl ammonium chlorides	0.25
Isopropyl alcohol	55.00
Other Ingredient(s):	45.50
Total	100.00

<u>BACKGROUND</u>: The registrant has submitted an acute toxicity package for the registration of this wipe. The package includes a label, Confidential Statements of Formula for the basic formulation and alternate formulation 1, a study for eye irritation (MRID 49494601) and a toxicity review done under D396553.

# **RECOMMENDATIONS:**

1. The study for eye irritation is **partially acceptable**. The Agency is only able to use the data on the neat test substance with no rinse. The Agency cannot use the data after the 4-second rinse or after the 30-second rinse.

2. The acute toxicity profile for 9480-4 is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity		?	Data Gap
Acute Dermal Toxicity	48660801	IV	Acceptable
Acute Inhalation Toxicity		?	Data Gap
Primary Eye Irritation	49494601	П	Partially Acceptable
Primary Skin Irritation	47122903	III	Acceptable
Skin Sensitization		?	Data Gap

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The policy on antimicrobial towelettes and wipes is under consideration by the Antimicrobial Division. Once the policy has been finalized, registrants will be informed if there are changes that need to be made regarding the registration process and if there are any additional data that must be submitted to the Division for review.

### LABELING

No labeling can be prescribed at the present time.